

**PATENT**/Docket No. PC26855A  
Appl. No. 10/658,164  
Filing Date: 9/9/2003  
Amendment dated June 6, 2007  
Reply to Office Action of March 6, 2007

### **REMARKS/ARGUMENTS**

#### **35 U.S.C. §112**

Claims 1-2, 5-11, 13-17,19-24, 27, 29-32, and 35-36 have been rejected under 35 U.S.C. §112 as being allegedly indefinite. The phrase "the sample taken from" has been deleted in Claim 1. In claim 5 the phrase "comprising a pharmaceutically active component" has been added. This provides an antecedent basis for the phrase in claim 6. In claim 23, the term "stirring" has been replaced by the term "contacting" which has antecedent basis in claims 1 and 22. In claim 27 the phrase "the buffer solution" has been changed to "the buffer" as suggested by the examiner. In claim 29 the pH range has been changed to 6 to 8 as suggested by the examiner. Claim 35 has been amended by deletion of the phrase "the sample taken from" has been deleted. The spelling of "befor" has been corrected. Reconsideration and withdrawal of these rejections under 35 U.S.C. §112 in view of these amendments is respectfully requested.

#### **Nonstatutory Obviousness-type Double Patenting Co-pending Application 10/658165 in View of Andonaegui et al.**

Claims 1-2, 5-11, 13-17,19-24, 27, 29-32, and 35 are provisionally rejected as being unpatentable over claims 1-3, 5-26, 28 and 33-36 of co-pending Application No. 10/658,165 in view of Andonaegui et al. Applicants respectfully point out that co-pending Application No. 10/658,165 is fundamentally different from the present application in that in co-pending Application No. 10/658,165 an emulsion is produced while the in method of the present application an emulsion does not form.

The importance of the emulsion in the co-pending Application No. 10/658,165 is illustrated on page 14 of the specification of the co-pending Application No. 10/658,165:

Any agitation apparatus, which can be used to prepare an emulsion, can be employed. Examples of suitable agitation apparatuses are the various laboratory shakers commercially available with or without temperature control and may agitate in an orbital, linear (reciprocal), or any other fashion.

Preferred agitation apparatuses are shakers in which the mixture contained in the receptacle is vigorously agitated. The shaker can move the receptacle horizontally, vertically, in a seesaw fashion or in any combination thereof. A particularly preferred shaker is a reciprocating shaker.

In discussing the apparatus used in the present application co-pending Application No. 10/658,165 notes that such apparatus does not generally produce the emulsion desired in the method of the co-pending Application No. 10/658,165. At page 14 of the co-pending Application No. 10/658,165 it states:

Although they might be able to form an emulsion under special circumstances typically the non-aqueous liquid composition and the aqueous dissolution medium will not form an emulsion by simple stirring such as in a paddle assembly. In these apparatuses the non-aqueous liquid composition generally floats on the surface of the aqueous dissolution medium. Therefore, the area of contact between these two components is smaller than in the method of the invention and the dissolution rate of the analyte may be lower.

Applicants respectfully note that as set forth beginning on page 12 line 25 of the present application it is desirable for the non-aqueous medium to spread on the surface of the dissolution medium. It is optimal if the non-aqueous forms an even layer on the surface of the dissolution medium (page 13 line 3). When the non-aqueous medium spreads across the surface of the dissolution medium, two distinct continuous liquid phases in contact with each other are formed.

In Andonaegui et al. the dissolution rate of theophylline in solid sustained release formulations was studied. Andonaegui et al. treat certain pellets with peanut oil before testing the dissolution rate. The pellets are placed in a stirred aqueous medium and the theophylline in this aqueous medium is measured over a period of time. Whether or not the pellets are treated with peanut oil, Andonaegui et al. always measure the rate of dissolution from a solid phase to a liquid phase. Thus, Andonaegui et al. never have two distinct continuous liquid phases in contact with each other. When Andonaegui et al. is combined with co-pending Application No. 10/658,165 there is no suggestion of two continuous liquid phases. In other words the

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combination of Andonaegui et al. with co-pending Application No. 10/658,165 does not lead to applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested.

**35 U.S.C. §103(a) Schapaugh et al (US 2004/0115822) in View of Andonaegui et al.**

Claims 1-2, 5-11, 13-17, 19-24, 27, 29-32, and 35 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Schapaugh et al. (US 2004/0115822) in view of Andonaegui et al. Applicants respectfully note that US 2004/0115822 is the published version of the co-pending Application No. 10/658,165 discussed above. For reasons set forth above, the combination of Andonaegui et al. with co-pending Application No. 10/658,165 does not lead to Applicants' invention.

Although there is overlap between the inventors of US 2004/0115822 and the inventors of the present application, the inventors of the two applications are not the same. The provisional applications corresponding to these two national applications were filed on different days. However, both US 2004/0115822 and the present application were filed on the same day and published on the same day. Applicants respectfully suggest that for a reference to be usable to show obviousness under 35 U.S.C. §103, it must qualify as a reference under 35 U.S.C. §102. When US 2004/0115822 published, the present application was already on file. Accordingly, US 2004/0115822 is not a reference under 35 U.S.C. §102(a) or 35 U.S.C. §102(b). Clearly, US 2004/0115822 is not a reference under 35 U.S.C. §102(d). As noted above, US 2004/0115822 and the present application were filed on the same day. An invention is constructively reduced to practice when an application is filed, although an applicant may, if necessary, prove an earlier date of invention. The present invention was constructively reduced to practice on the exact day when US 2004/0115822 was filed. Accordingly, 2004/0115822 was not filed before the invention of the present invention, and US 2004/0115822 is not available as a reference under 35 U.S.C. §102(e)(1). US 2004/0115822 has not issued as a patent and thus is not available as a reference under 35 U.S.C. §102(e)(2). There is no section of 35 U.S.C. §102 which would allow the use of US 2004/0115822 as a reference. Accordingly, US 2004/0115822 is not available as a

reference under 35 U.S.C. §103. Reconsideration and withdrawal of this rejection is respectfully requested.

**35 U.S.C. §103(a) Dunn et al. (US 5,721,359) in View of Conti et al. and Andonaegui et al.**

Claims 1-2, 5-11, 13-17, 19-24, 27, 29-32, and 35 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Dunn et al. (US 5,721,359) In View of Conti et al. and Andonaegui et al. As set forth above, in the Applicants' method as described beginning on page 12 line 25 of the present application it is desirable for the non-aqueous medium to spread on the surface of the dissolution medium. It is optimal if the non-aqueous forms an even layer on the surface of the dissolution medium (page 13 line 3). When the non-aqueous medium spreads across the surface of the dissolution medium, two distinct continuous liquid phases in contact with each other are formed.

In making this rejection the examiner states that in the dissolution test described in Dunn et al. the non-aqueous liquid composition and the aqueous are agitated with a paddle. The dissolution test described in Example 7 of Dunn et al. does not allow contact between the aqueous dissolution medium, and the non-aqueous medium. The test is described in Dunn et al. as follows:

100 mg samples of crystalline ceftiofur free acid, amorphous ceftiofur free acid (prepared as described in Example 1) and crystalline ceftiofur hydrochloride, which were all prepared as oil formulations as described in Example 4 above, were loaded into teflon dissolution cells and sealed with a constant surface area dialysis membrane. The loaded cells were placed in a standard dissolution apparatus containing 500 ml of pH 7 aqueous dissolution media which was stirred by a 50 RPM rotating paddle.


Applicants respectfully note that the non-aqueous compositions are placed in a dissolution cell and sealed with a constant surface dialysis membrane. Accordingly, the non-aqueous composition is separated from the aqueous dissolution medium. Clearly Dunn et al. do not create

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two distinct continuous liquid phases in contact with each other, and thus the reference does not disclose applicant's invention.

As set forth above, Andonaegui et al. measure the rate of dissolution from a solid phase to a liquid phase. Thus Andonaegui et al. never have two distinct continuous liquid phases in contact with each other. Conti et al. relate to measurements of the rate of drug dissolution from drug containing microparticles in an aqueous medium. In other words, Conti et al. relate to the dissolution of a drug from a solid phase into an aqueous phase. Conti et al. do form two distinct continuous liquid phases in contact with each other. Thus, no combination of Dunn et al., Conti et al., or Andonaegui et al. discloses or suggests Applicants' invention. Reconsideration and withdrawal of this rejection is respectfully requested. Reconsideration and withdrawal of all rejections and allowance of this application is respectfully requested.

Respectfully submitted,

  
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Date: JUNE 6, 2007

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